

Serial No.: 09/994,671
Atty. Docket No.: 100858.00106

REMARKS

In view of the above amendments, favorable consideration in this application is respectfully requested. By this Preliminary Amendment, claims 3-28 have been added.. Accordingly, claims 1-28 remain pending in the application, including independent claims 1, 2, 3, 11, 17 and 19-23. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment, captioned "Version with markings to show changes made."

In the event there are any questions relating to this Amendment or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME COMISKY & McCAULEY LLP, Deposit Account No. 23-2185 (100858.00106). In the event that a petition for an extension of time is required to be submitted herewith and in the event that

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a separate petition does not accompany this response, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized above.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 3-28 have been added, as follows:

--3. A method of storing a sterilized chemical composition for use in a sterile environment and maintaining the sterilization shelf life of the sterilized chemical composition for a prolonged period of time in a storage area, said sterilized chemical composition being contained in a sealed container, said sealed container being hermetically sealed in successive first and second hermetically sealed container enclosures, and a shipping enclosure to form a closed shipping package adapted to be transported, comprising the steps of:

removing the sterilized chemical composition contained in the sealed container and the first and second hermetically sealed container enclosures from the shipping enclosure of the closed shipping package;

transporting the sterilized chemical composition contained in the sealed container and the first and second hermetically sealed container enclosures to the storage area;

storing the sealed container enclosed in the first and second hermetically sealed container enclosures in the storage area for a period of time;

after the period of time, removing the second hermetically sealed container enclosure and transporting the sealed container contained in the first hermetically sealed container enclosure to the sterile environment for use; and

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removing the first hermetically sealed container enclosure in the sterile environment for use of the sterilized chemical composition in the sterile environment.

4. The method of claim 3, wherein the storage area is a sterile storage area.
5. The method of claim 3, wherein said chemical composition is isopropyl alcohol sterilized in said sealed container by gamma radiation in the range of about 20 to 40 kilograys.
6. The method of sterilization of claim 3, wherein said sealed container is a container with a cap closure.
7. The method of sterilization of claim 3, wherein said chemical composition is isopropyl alcohol.
8. The method of sterilization of claim 3, wherein each of said first and second sealing layers is formed of a single layer of closed cell polyethylene.
9. The method of sterilization of claim 3, wherein said irradiating step comprises subjecting the closed shipping package to gamma radiation in the range of about 20 to 50 kilograys.
10. The method of claim 3, wherein said sealed container is an aerosol container pressurized with an inert gas.

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11. A method of sterilizing chemical composition contained in an aerosol container comprising the steps of:

providing an aerosol container having an internal volume;

charging the internal volume of the aerosol container with a quantity of chemical composition;

pressurizing the internal volume of the aerosol container with an inert gas and sealing the aerosol container;

hermetically sealing the aerosol container in a first sealing layer to form a first hermetically sealed container enclosure;

hermetically sealing said first hermetically sealed container enclosure in a second sealing layer to form a second hermetically sealed container enclosure;

enclosing said second container enclosure in a shipping container to form a closed shipping package; and

externally irradiating said closed shipping package at a predetermined radiation level for a predetermined time interval to simultaneously sterilize said chemical composition, said aerosol container, and said first and second hermetically sealed container enclosures.

12. The method of sterilization of claim 11, wherein said chemical composition comprises a disinfectant liquid.

13. The method of sterilization of claim 12, wherein said disinfectant liquid comprises isopropyl alcohol and said inert gas is nitrogen.

14. The method of sterilization of claim 11, wherein said first and second sealing layers are formed of closed cell polyethylene and wherein said steps of hermetically sealing the first and second sealing layers comprise heat sealing.

15. The method of sterilization of claim 11, wherein said irradiating step comprises subjecting the closed shipping package to gamma radiation in the range of about 20 to 40 kilograys.

16. The method of sterilization of claim 15, wherein the irradiating step comprises applying the gamma radiation to the closed shipping package in a plurality of directions.

17. A method of sterilizing a disinfecting liquid contained in an aerosol container comprising the steps of:

providing an aerosol container having an internal volume;

charging the internal volume of the aerosol container with a quantity of disinfecting liquid;

pressurizing the internal volume of the aerosol container with an inert gas and sealing the aerosol container;

sealing the aerosol container within a plurality of successively nested hermetic sealing layers to form a hermetically sealed container enclosure, said sealing step comprising the further steps of;

hermetically sealing the aerosol container in a first sealing layer to form a first hermetically sealed container enclosure;

hermetically sealing said first hermetically sealed container enclosure in a second sealing layer to form a second hermetically sealed container enclosure;
inserting at least one second hermetically sealed container enclosure into a carton member to form a closed shipping package; and externally irradiating said closed shipping package and said aerosol container therewithin at a predetermined radiation level for a predetermined time interval to simultaneously sterilize said disinfecting liquid, said aerosol container, and said plurality of successively nested hermetic sealing layers.

18. The method according to claim 17, wherein the disinfecting liquid is alcohol.

19. A method of storing a sterilized chemical composition and maintaining the sterilization shelf life of the sterilized chemical composition for a prolonged period of time in a sterile environment, said sterilized chemical composition being contained in a sealed container, said sealed container being hermetically sealed in successive first and second hermetically sealed container enclosures, and a shipping enclosure to form a closed shipping package adapted to be transported, comprising the steps of:

removing the sealed container and the successive first and second hermetically sealed container enclosures from the shipping enclosure of the closed shipping package;

storing the sealed container and successive first and second hermetically sealed container enclosures in the sterile environment for a period of time;

after the period of time, removing the second hermetically sealed container and the first hermetically sealed container enclosure within the sterile environment for use of the sterilized chemical composition in the sterile environment.

20. A method of sterilizing a chemical composition contained in a sealed container comprising the steps of:

providing a container having an internal volume;

charging the internal volume of the container with a quantity of chemical composition;

sealing the internal volume of the container to form a sealed container;

hermetically heat sealing the container in a first single-layer sealing layer to form a first hermetically heat-sealed container enclosure;

hermetically heat sealing said first hermetically sealed container enclosure in a second single-layer sealing layer to form a second hermetically heat-sealed container enclosure;

enclosing said second hermetically heat-sealed container enclosure in a shipping container to form a closed shipping package; and

externally irradiating said closed shipping package at a predetermined radiation level for a predetermined time interval to simultaneously sterilize said chemical composition, said sealed container, and said first and second hermetically heat-sealed container enclosures.

21. A method of sterilizing a chemical composition contained in a sealed container comprising the steps of:

providing a container having an internal volume;

charging the internal volume of the container with a quantity of chemical composition;

sealing the internal volume of the container to form a sealed container;

hermetically heat sealing the container in a first single-layer sealing layer to form a first hermetically heat-sealed container enclosure;

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enclosing said first hermetically heat-sealed container enclosure in a second single-layer sealing layer to form a second container enclosure;

enclosing said second container enclosure in a shipping container to form a closed shipping package; and

externally irradiating said closed shipping package at a predetermined radiation level for a predetermined time interval to simultaneously sterilize said chemical composition, said sealed container, said first hermetically heat-sealed container enclosure and said second container enclosure.

22. A method of storing a sterilized chemical composition and maintaining the sterilization shelf life of the sterilized chemical composition for a prolonged period of time in a sterile environment, said sterilized chemical composition being contained in a sealed container, said sealed container being hermetically sealed in a first hermetically sealed container enclosure and a second sealing layer enclosure and a shipping enclosure to form a closed shipping package adapted to be transported, comprising the steps of:

removing the sealed container, the second sealing layer enclosure and the first hermetically sealed container enclosure from the shipping enclosure of the closed shipping package;

storing the sealed container, the second sealing layer and the first hermetically sealed container enclosure in the sterile environment for a period of time; and

after the period of time, removing the first hermetically sealed container enclosure within the sterile environment for use of the sterilized chemical composition in the sterile environment.

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23. A sterilized closed shipping package comprising:

a sterilized sealed aerosol container having an internal volume charged with a quantity of sterilized chemical composition and pressurized with an inert gas;

a sterilized first hermetically sealed container enclosure with a first sealing layer hermetically sealing said sealed aerosol container within said first hermetically sealed container enclosure;

a sterilized second hermetically sealed container enclosure with a second sealing layer hermetically sealing said first hermetically sealed container enclosure within said second hermetically sealed container enclosure; and

a sterilized closed shipping container enclosing said first and second hermetically sealed container enclosures and said sealed aerosol container to form a closed shipping package, the closed shipping package irradiated to simultaneously sterilize said chemical composition, said aerosol container, and said first and second hermetically sealed container enclosures..

24. The sterilized closed shipping package of claim 23, wherein said chemical composition comprises a disinfectant liquid.

25. The sterilized closed shipping package of claim 24, wherein said disinfectant liquid comprises isopropyl alcohol and said inert gas is nitrogen.

26. The sterilized closed shipping package of claim 23, wherein said first and second sealing layers are closed cell polyethylene which are sealed by heat sealing.

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27. The sterilized closed shipping package of claim 23, wherein the closed shipping package is irradiated by subjecting the closed shipping package to gamma radiation in the range of about 20 to 40 kilograys.

28. The sterilized closed shipping package of claim 27, wherein the closed shipping package is irradiated by applying the gamma radiation to the closed shipping package in a plurality of directions.--